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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,582

08/22/2006

Kenichi Kudo

YAMAP1004US

5887

43076

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07/21/2010

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/569,582	<b>Applicant(s)</b> KUDO ET AL.	
	<b>Examiner</b> HASAN S. AHMED	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of applicants' amendment and remarks, filed on 26 April 2010.

\* \* \* \* \*

### ***Status of the Claims***

Claims 3-12 have been canceled. Claims 1 and 2 are under active prosecution and have been rejected.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2004/0009218 ("Kitamura") in view of U.S. Patent No. 6,677,142 ("Weissmuller") (both references were cited in the IDS filed on 23 February 2006).

Kitamura teaches a biodegradable article formed from an entirely linear amylose that has a weight average molecular weight of not less than 100 kDa (equivalent to a degree of polymerization of 615) (reading on claim 1) and has a narrow molecular weight distribution, which is obtained by enzyme-synthesis using phosphorylase (reading on claim 2) (see p. [0020]).

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Kitamura further explains that the disclosed biodegradable article is formed from enzyme-synthesized amylose using phosphorylase, wherein the enzyme-synthesized amylose is composed of glucose monomers exclusively bonded by alpha-1,4-glucosidic linkage (reading on claim 1) (see p. [0021]). The disclosed enzyme-synthesized amylose has a dispersity ( $M_w/M_n$ ) of not more than 1.25 (see p. [0027]) (reading on claim 1).

Kitamura explains that the disclosed biodegradable article is beneficial in that it has excellent biodegradability, transparency, processability, and strength characteristics (see p. [0021]).

Kitamura teaches application of the disclosed biodegradable material in pharmaceuticals (see p. [0055] and p. [0060]), medical products (see p. [0060]), medical material (see p. [0063] and [0067]), and medical appliances (see p. [0063] and [0067]). However, Kitamura does not explicitly teach use of the biodegradable material in tablets.

Weissmuller teaches alpha-1,4-glucan chain containing polysaccharides (see col. 1, lines 11-13). The disclosed polysaccharides may be used as tablet fillers (see col. 6, lines 21-23).

Kitamura or Weissmuller do not explicitly teach use of the glucan containing polysaccharides as disintegrants, however, “Products of identical chemical composition can not have mutually exclusive properties.’ A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the

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properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).” See MPEP 2112.01.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a disintegrant for tablets consisting of an alpha-1,4-glucan having a degree of polymerization of not less than 180 and less than 1230 and a dispersity of not more than 1.25, as taught by Kitamura in view of Weissmuller. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a product because it has excellent biodegradability, transparency, processability, and strength characteristics, as explained by Kitamura (see above).

\* \* \* \* \*

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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1. Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6-12, 18, and 21 of copending Application No. 10/333,267 ('267) in view of U.S. Patent No. 6,677,142 ("Weissmuller"). Although the conflicting claims are not identical, they are not patentably distinct from each other because '267 claims a biodegradable article formed from enzyme-synthesized amylose, wherein the enzyme-synthesized amylose is composed of glucose monomers exclusively bonded by alpha-1,4-glucosidic linkage, and the enzyme-synthesized amylose has a weight average molecular weight of not less than 100 kDa, and the enzyme-synthesized amylase has a molecular weight distribution of not more than 1.25 (claim 1). '267 does not explicitly teach use of the biodegradable material in tablets. Weissmuller teaches alpha-1,4-glucan chain containing polysaccharides (see col. 1, lines 11-13). The disclosed polysaccharides may be used as tablet fillers (see col. 6, lines 21-23). '267 or Weissmuller do not explicitly teach use of the glucan containing polysaccharides as disintegrants, however, "Products of identical chemical composition can not have mutually exclusive properties.' A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." See MPEP 2112.01. See 35 USC 103 rejection, above.

As such, a person of ordinary skill in the art at the time the instant application was filed would have found claims 1 and 2 of the instant application prima facie obvious

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over claims , 2, 4, 6-12, 18, and 21 of copending Application No. 10/333,267 ('267) in view of U.S. Patent No. 6,677,142 ("Weissmuller").

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed on 26 April 2010 have been fully considered but they are not persuasive.

Applicants argue that Weissmuller is not combinable with Kitamura because Weissmuller discloses conventional alpha-1,4 glucans as tablet fillers (see remarks, pages 3-5.

Examiner respectfully submits that Kitamura also discloses use of the disclosed biodegradable material in pharmaceuticals, medical products, and medical material (see substantive rejection, above). Weissmuller was invoked as evidence of the general use of alpha-1,4 glucans in tablets.

Applicants argue that one skilled in the art would not expect the amylose disclosed by Kitamura to be superior as a disintegrant for tablets. See remarks, pages 5-6.

Examiner respectfully submits that Kitamura lists excellent biodegradability as one of the benefits of the disclosed amylose (see p. [0021]). Kitamura further teaches use of the disclosed amylose in pharmaceuticals and medical material (see p. [0055], [0060], [0063], and [0067]). Biodegradability and disintegration are equivalent concepts.

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As such, examiner respectfully submits that a material with excellent biodegradability will result in disintegration properties when applied to pharmaceuticals, such as tablets.

Applicants argue that those skilled in the art would consider that a tablet made using the amylose disclosed by Kitamura would have excellent strength and thus would not disintegrate easily. See remarks, page 6.

Examiner respectfully submits that amylose disclosed by Kitamura meets the structural limitations recited in claim 1. As indicated in the substantive rejection, “‘Products of identical chemical composition can not have mutually exclusive properties.’ A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).” See MPEP 2112.01.

Applicants apply the above arguments to the obviousness-type double patenting rejection. See remarks, page 7.

Please refer to the responses above.

\* \* \* \* \*

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. S. A./  
Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615

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